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**APPLICATION FOR UNITED STATES LETTERS PATENT**

for

**METHOD FOR MONITORING BOLUS DELIVERY**

by

**MARY M. MORRIS**

ATTORNEY/AGENT OF RECORD:

Elisabeth L. Belden, Reg. No. 50,751  
Telephone: (763) 514-4083  
No. 27,581

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## **METHOD FOR MONITORING BOLUS DELIVERY**

### **TECHNICAL FIELD**

The present invention relates to the field of implantable drug infusion devices and more particularly to a method for monitoring boluses delivered by an implantable drug infusion device through an infusion catheter.

### **BACKGROUND**

Implantable drug infusion devices are used to provide patients with programmable long-term dosage or infusion of a drug or any other therapeutic agent. These devices typically include a pump and a catheter attached to the pump and extending to a target site through which boluses of infusate are delivered. It is desirable to monitor such devices to verify bolus delivery or to identify causes of unsuccessful bolus delivery, such as leakage or occlusion.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

The following drawings are illustrative of particular embodiments of the invention and therefore do not limit its scope, but are presented to assist in providing a proper understanding of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. The present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements, and:

FIG. 1 is a schematic diagram of an implanted drug infusion device wherein embodiments of the present invention may be practiced;

FIG. 2 is a flowchart detailing a method according to one embodiment of the present invention;

FIG. 3A is a plot of pressure versus time measured during a bolus delivery in leaky device;

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FIG. 3B is a plot of pressure versus time measured during a bolus delivery in an occluded device; and

FIG. 3C is a plot of pressure versus time measured during a successful bolus injection.

### **DETAILED DESCRIPTION OF THE DRAWINGS**

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides a practical illustration for implementing exemplary embodiments of the invention.

FIG. 1 is a schematic diagram of an implanted drug infusion device wherein embodiments of the present invention may be practiced. FIG. 1 illustrates the device including a pump 20, implanted in an abdominal region of a patient, and an infusion catheter 25, coupled to pump 20 via a connector 24, extending into a superior vena cava 12 via a subclavian vein 10. FIG. 1 further illustrates catheter 25 including a valve 27 positioned in proximity to a distal end 26; valve 27 may be any type of valve known to those skilled in the art, for example a slit valve, a sleeve valve or a small hole valve. Pump 20 includes a reservoir, which may be refilled via an injection port 21, and a peristaltic pump, which propel a bolus of infusate out from the reservoir through catheter 25; an example of such a pump is the Medtronic SynchroMed™. Bolus volumes according to embodiments of the present invention may range between approximately 0.05 mL and approximately 1 mL and delivery times may range between approximately 1 minute and approximately 60 minutes.

According to one embodiment of the present invention, as illustrated in FIG. 1, pump 20 further includes a catheter port 22 through which a physician may insert a needle coupled to an external pressure transducer to monitor intra-catheter pressure versus time as a bolus of infusate is delivered through catheter 25; such means to monitor pressure are well known to those skilled in the art.

Alternately a pressure transducer may be built into pump 20 or catheter connector 24 to measure the intra-catheter pressure. Analysis of the intra-catheter pressure versus time during bolus delivery can be used to verify successful bolus delivery or to diagnose problems with the implantable infusion device, which prevent successful bolus delivery.

FIG. 2 is a flowchart detailing a method according to one embodiment of the present invention wherein a measured pressure versus time is analyzed. FIG. 1 illustrates a first step 200 of delivering a bolus from a pump to a catheter and a second step 210 of measuring intra-catheter pressure versus time as the bolus is being delivered. Initial analysis of the measured pressure versus time determines if pressure has increased after the first 10 seconds of bolus delivery, 220; if pressure has not increased, the method infers that there is a large breach or disconnect in the device, 215, but if pressure has increased a next analysis step, 230, is performed. At step 230, the method analyzes the pressure increase versus time to determine if it is approximately linear; if the measured pressure increase is non-linear, the method infers that there is a small leak or breach in the catheter, 225, but if the increase is approximately linear, a next analysis step, 240, is performed. At step 240, the method analyzes the measured pressure versus time to determine if a pressure decrease follows the pressure increase; if the pressure continues to rise, the method infers that the catheter is occluded, 235, while, if the pressure rises and then falls, the method infers that the bolus has been successfully delivered, 245. Methods according to some embodiments of the present invention include controls to abort bolus delivery at any of the inference points 215, 225 or 235.

## **EXAMPLES**

FIGs. 3A-C present plots of pressure in mmHg (ordinate) versus time in seconds (abscissa) collected via an external transducer coupled to a needle inserted within catheter ports, i.e. port 22 shown in FIG. 1, of exemplary devices.

Each device included a valved infusion catheter implanted within a venous system.

FIG. 3A is a plot of pressure versus time measured during a bolus delivery from a pump through an infusion catheter including a sleeve valve wherein there was a leak at a coupling between the catheter and the pump. FIG. 3A illustrates a non-linear increase in pressure, from approximately 71 mmHg to approximately 177 mmHg, in between a pump start point 305 and a pump stop point 309 and corresponds to inference point 225 presented in FIG. 2.

FIG. 3B is a plot of pressure versus time measured during a bolus delivery from a pump through an infusion catheter, including a small hole valve, wherein the catheter was occluded by thrombus. FIG. 3B illustrates a rise in pressure, from approximately 59 mmHg to approximately 187 mmHg, between a pump start point 315 and a pump stop point 319 and corresponds to inference point 235 presented in FIG. 2.

FIG. 3C is a plot of pressure versus time measured during a successful bolus injection from a pump through a catheter including a slit valve. FIG. 3C illustrates an approximately linear pressure increase between pump start point 325 (~73 mmHg) and a maximum pressure point 326 (~110 mmHg at ~30-35 seconds) and then a decrease in pressure from point 326 to pump stop point 329 (~107 mmHg); FIG. 3C corresponds to inference point 245 presented in FIG. 2.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.